In the Supreme Court of the United States

OCTOBER TERM, 1956

No. 309

2600 STATE DRUGS, INC., A CORPORATION, EDWARD KRAVETZ, MELBURN HOLTZMAN, RAYMOND HOLTZMAN, PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINION BELOW

The opinion of the Court of Appeals (Pet. App. 1a–8a) is not yet reported.

JURISDICTION

The judgment of the Court of Appeals (Pet. App. 1a–8a) was entered on July 11, 1956. The petition for a writ of certiorari was filed on August 10, 1956. The jurisdiction of this Court is invoked under 28 U. S. C. 1254 (1).

QUESTION PRESENTED

Whether, under its power to regulate commerce, Congress can prohibit the intrastate sale-without-

prescription of dangerous drugs which have been shipped in interstate commerce and held for sale.

STATUTE INVOLVED

The Federal Food, Drug, and Cosmetic Act of June 25, 1938, 52 Stat. 1040, as amended, 21 U. S. C. 301 et seq., provides in pertinent part:

> 21 U. S. C. 331. *Prohibited acts.*
>
> The following acts and the causing thereof are prohibited:
>
> * * * * *
>
> (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.
>
> * * * * *
>
> 21 U. S. C. 333. *Penalties—(a) Violation of section 331.*
>
> Any person who violates any of the provisions of section 331 of this title shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; * * * .

21 U. S. C. 353 (b) *Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws.*

(1) A drug intended for use by man which—

(A) is a habit-forming drug to which section 352 (d) of this title applies; or

(B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(C) is limited by an effective application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug,

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

STATEMENT

Petitioners were found guilty by the District Court for the Northern District of Illinois, sitting without a jury, on an information (Pet. App. 9a–12a) which

charged the sale, without prescription, of drugs bearing on their container the legend, "Caution, federal law prohibits dispensing without prescription", contrary to the provisions of 21 U. S. C. 353 (b) (1), *supra*, p. 3, which act resulted in the drugs being misbranded while held for sale in violation of 21 U. S. C. 331 (k), *supra*, p. 2 (R. 1053–1054). The corporate petitioner was fined $250 cumulatively on each of the four counts of the information; the individual petitioners were each sentenced to a total of three months' imprisonment and fined $250 cumulatively on the counts naming them (R. 1066–1068).

Petitioners do not contest here, nor did they before the Court of Appeals, the finding of the district court that they had violated the terms of the statute. They argue that Congress exceeded its authority to regulate commerce when it proscribed an intrastate sale-without-prescription of dangerous drugs that had been shipped in interstate commerce. The Court of Appeals overruled this contention on the authority of *United States* v. *Sullivan*, 332 U. S. 689, and *McDermott* v. *Wisconsin*, 228 U. S. 115 (Pet. App. 6a–8a).[1]

ARGUMENT

The constitutional issue presented by this case, whether Congress can, under its power to regulate interstate commerce, penalize the local sale-without-prescription of a dangerous drug which has been shipped through the channels of interstate commerce,

[1] The Court of Appeals also dismissed petitioners' argument that the statute was unconstitutionally vague (Pet. App. 1a–6a), and petitioners do not contest that holding here.

has been affirmatively answered by this Court in *United States* v. *Sullivan*, 332 U. S. 689, 696–698, which upheld a criminal sanction imposed under the Federal Food, Drug, and Cosmetic Act against a local sale of a dangerous drug which had not been adequately labeled.

Petitioners' attempt to distinguish the *Sullivan* decision (Pet. 7–8) on the ground that it involved mislabelling of the article itself, whereas here the article sold did carry proper labelling, the misbranding resulting from the act of selling without prescription.[2] But, while the *Sullivan* decision does refer to misbranding because the violation there charged was misbranding, the constitutional problem arising from the fact of local sale is not different. In the *Sullivan* case, as here, the article involved had been properly labeled during its interstate shipment. The constitutional question before the Court was whether congress had the power to prevent a local druggist from taking pills out of the properly shipped bottle and selling them locally without proper labelling. When the Court held that Congress had such power, it necessarily decided the question here involved—*i. e.*, that Congress could forbid the sale entirely, without prescription.

The constitutional basis upon which the statutes in both the *Sullivan* case and this case rest is the power

[2] The *Sullivan* decision was handed down prior to the Durham-Humphrey amendment to the Federal Food, Drug, and Cosmetic Act, involved here, which added to the types of misbranded drugs those of a toxic nature safe only on prescription of a physician. Act of October 26, 1951, 65 Stat. 648, 21 U. S. C. 353 (b), *supra*, p. 3.

of Congress to prevent the channels of interstate commerce from being used to the detriment of public health. To that end, the Court recognized in *Sullivan* that the Food and Drug Act was intended to extend its coverage "to every article that had gone through interstate commerce until it finally reached the ultimate consumer", 332 U. S. at pp. 696–697. The ruling that such coverage was constitutional is decisive here. No attack is or could be made on the reasonableness of the Congressional finding that certain drugs are too dangerous to be dispensed without prescription. The only issue is whether Congress has the right to follow the drug beyond the interstate shipment itself to the ultimate consumer. That question was decided affirmatively by *Sullivan*. See also *United States* v. *Walsh*, 331 U. S. 432, 434, 437–438; *United States* v. *Dotterweich*, 320 U. S. 277, 280; *McDermott* v. *Wisconsin*, 228 U. S. 115, 128.

CONCLUSION

For the foregoing reasons, we submit that this petition for a writ of certiorari should be denied.

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What may be a misleading statement in the brief filed by the United States requires comment. On page 5 of the Brief in Opposition filed in behalf of the respondent, it is acknowledged that a factual distinction between the case of *United States* v. *Sullivan,* (332 U. S. 789), and the instant case exists. This factual difference, however, is so recharacterized that a misleading conclusion is drawn by the respondent. The issue in the *Sullivan* case concerned the lack of labeling *at the time of local sale to the purchasers.* No question was present concerning the nature of the labeling at the time the goods were placed in inter-state commerce by the manufacturer.

In the *Sullivan* case the purchasers were not given the information or directions for use prescribed by the manufacturer. In the instant case the manufacturer's labels were preserved intact and delivered to the purchasers on the bottles. The constitutional question in the *Sullivan* case was not the same because the misbranding, *i.e.*, the obliteration through removal of the label, was *actual*.

It is stated in the respondent's brief that when the Court held in the *Sullivan* case that Congress could prohibit the removal of labels, that it necessarily decided the question here. This statement flies in the face of the opinion of the Supreme Court. The majority opinion, as well as the minority opinion, devoted considerable space to consideration whether the removal of the labels was a violation of the law because Congress had a right to provide that the message of the manufacturer for the purposes of use be undisturbed.

The issue in the instant case does not lie in the question whether Congress may preserve the integrity of an article and its label. The issue is whether Congress can, in spite of and in addition to, legislation respecting the label, regulate conditions of local sale so as to require a physician's prescription. There is no justification for the conclusion drawn by the respondent, that the Supreme Court decided the question before us here. It has cited not one sentence from the decision of the Supreme Court in the *Sullivan case* which would support this view.

Had the Supreme Court considered that Congress could regulate conditions of local sale of drugs under the commerce power identical with that exercised under the power to tax, as in the case of narcotic legislation, it could easily

have said so and made short shrift of the constitutional question presented in the *Sullivan* case. This it did not do.

It is significant that the reply brief of the respondent in no way refers to the means used by Congress to regulate drugs in this instance. Nothing is said in justification of the technique wherein Congress has created a legal fiction in order to achieve its end, that is, calling a true label false for the purpose of imposing a criminal penalty.

Although it is doubtful that such was its intent, if the Supreme Court really meant in the *Sullivan* case that Congress had justification for the Durham-Humphrey amendment, then this is a perfect factual case in which the Supreme Court may exercise its jurisdiction and say precisely what the United States said it meant. If the Supreme Court did not, as your petitioners believe, then this Court should accept jurisdiction to correct a dangerous form of legislative abuse. The technique prescribed in the Durham-Humphrey amendment is a device which can be easily contrived to change the character of any act and bring it within the Federal jurisdiction contrary to law.

Respectfully submitted,

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